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U. S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

RE: Docket Number 02N-0466

Dear Food and Drug Administration,

My purpose of writing this letter to this administration is to express my opinion on the proposed testing of smallpox on a group of forty preschool age children. My opinion on the matter is that, while these tests may provide information to the public about the reintroduction of smallpox vaccinations, the tests will put these forty children and others at risk. Ultimately, I feel that these tests should not be conducted. First of all, the testing may not provide adequate results to safely conclude the usefulness of the vaccine and secondly the vaccinations may cause serious illness or death in these young children.

The testing that is proposed only calls for a random sample of forty children aged two to five. I question whether this will be an accurate representation of all children of these ages in the United States. A group of forty children is a rather small sample of the children in this country. Obviously, some children in the country will react differently from the children in the study. Another fault with this proposed test is that the vaccine cannot be tested unless these children are subjected to a strain of smallpox after the vaccination. If the vaccination is not adequate enough to ward off the disease, these children will be subjected to an illness to which they are not properly vaccinated against. In short, this test will not result in any useful data unless the children are again subjected to the disease.

02N-0466

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My second topic of concern is the safety of the children. The diluted vaccination has already been tested on adults but children may react very differently to the vaccination. There is a risk associated with the vaccination itself. It may harm or threaten the children's lives. The vaccinations may cause scarring of the tissue while it scabs over. Small children may pick at their scabs and risk the infection of those who may come into contact with them. The children will also have to be observed in the days following the vaccination. This would require the parents of the children to constantly monitor the children for any abnormalities caused by the vaccination and to keep the area of the vaccination protected from curious fingers. This responsibility might keep a parent away from his/her job and add tension to the home for a few days to a few weeks. If a child were to touch the infected area and then touch his eye, he might risk blindness. I feel that these risks and burdens should not be placed on these young children and their families.

In conclusion I feel that the proposed testing should not be carried out. The testing itself has flaws and may put these children and their families at risk. I believe that there are better ways to go about the smallpox vaccination. Instead of administering the vaccine to all, it can be given to those who have or may come in contact with the disease. I do not feel it is necessary to vaccinate all Americans because this procedure would be full of unknowns and inherent risks.

Sincerely,

Jeremy Anderson